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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/104,063 06/24/98 LEE

J

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HM12/1222

GENENTECH INC

1 DNA WAY

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EXAMINER

ULM, J

ART UNIT

PAPER NUMBER

1646

DATE MAILED:

12/22/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/104,063

Applicant(s)
Lee et al.

Examiner
John Ulm

Group Art Unit
1646



☒ Responsive to communication(s) filed on Oct 23, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 20-23, 25, and 27-33 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 20-23, 25, and 27-33 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 10

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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- 1) Claims 20 to 23, 25 and 27 to 33 are pending in the instant application.
- 2) Any objection or rejection of record which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.
- 3) The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- 4) Claims 20 to 23, 25 and 27 to 33 are rejected under 35 U.S.C. § 101 because they are drawn to an invention with no apparent or disclosed specific and substantial credible utility for those reasons of record in section 4 of Paper Number 8.

Applicant has traversed this rejection on the premise that the claimed polynucleotide encodes a polypeptide which can be employed as a cell marker for monocytes and peripheral blood lymphocytes and the employment of that polypeptide as a cell marker is a credible, specific and substantial utility. The employment of a protein of the instant invention, or a nucleic acid encoding that protein, as a tissue specific marker is not a substantial or specific utility. All cDNAs encoding human proteins can invariably be classified into two categories, those which are expressed in a tissue or developmentally specific manner and those which are expressed ubiquitously. It can be alleged that any polynucleotide encoding a protein which is expressed in a tissue specific manner can be employed to detect the tissue or cell type in which it is expressed in a sample. Alternately, a polynucleotide encoding a human protein which is expressed ubiquitously can be employed to detect the presence of any human tissue in a sample. Such utilities are analogous to the assertion that a particular protein can be employed as a molecular weight marker

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or that any fragment of DNA of a natural origin can be employed as a chromosomal marker, neither of which is a specific or substantial utility.

One could just as readily argue that any purified compound having a known structure could be employed as an analytical standard in such processes as nuclear magnetic resonance (NMR), infrared spectroscopy (IR), and mass spectroscopy as well as in polyacrylamide gel electrophoresis (PAGE), high performance liquid chromatography (HPLC) and gas chromatography. None of these processes could be practiced without either calibration standards having known molecular structures or, at least, a range of molecular weight markers having known molecular weights. It was just such applications that the court appeared to be referring to when it expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation (*Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966)). Because the steroid compound which was the subject of that decision had a known structure and molecular weight it could have readily been employed as a molecular standard at that time. However, the court held that a process of producing that compound did not have specific and substantial utility because the compound produced thereby did not have a specific and substantial utility.

To grant Applicant a patent encompassing an isolated polynucleotide encoding a naturally occurring human protein of as yet undetermined biological significance would be to grant Applicant a monopoly "the metes and bounds" of which "are not capable of precise delineation". That monopoly "may engross a vast, unknown, and perhaps unknowable area" and "confer power

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to block off whole areas of scientific development, without compensating benefit to the public” (*Brenner v. Manson, Ibid*). To grant Applicant a patent on the claimed polynucleotide based solely upon an assertion that the protein encoded thereby can be employed as a tissue or cell marker is clearly prohibited by this judicial precedent since the compensation to the public is not commensurate with the monopoly granted. This is particularly relevant to the instant application in light of the Bleuel et al. publication (P.N.A.S. 94:1925-1930, Mar. 1997, cited by Applicant) since this reference discloses that the protein encoded by the claimed nucleic acid is clinically significant as a co-receptor for HIV. Nothing in the instant specification appears to even suggest a role for the disclosed protein in HIV infection. It is just such a situation that the court appeared to be referring to in the text quoted above.

Applicant’s reference to Patent Number 6,087,475 as establishing a patentable utility for the protein encoded by the claimed nucleic acid is not persuasive because each application is examined on its own merits. In the decision of *In re Hutchison*, 69 USPQ 138 (CCPA, 1946), the court held that

“We are not concerned, of course, with the allowed claims in either the patent or in this application. The sole question for our determination is whether the six article claims on appeal were properly rejected below, and this we pass upon without further reference to, and without comparing them with, the claims in the patent or the claims which stand allowed in this application.”

In essence, the position in the instant application that each application is examined on its own merits can be found in the judicial precedent cited above. The rejections in the instant application will only be withdrawn if they are shown to be legally or factually unsound.

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5) Claims 20 to 23, 25 and 27 to 33 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to use the instant invention for those reasons given above with regard to the rejection of these claims under 35 U.S.C. § 101.

6) Applicant's arguments filed 23 October of 2000 have been fully considered but they are not persuasive for those reasons given above.

7) **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.


JOHN ULM
PRIMARY EXAMINER
GROUP 1800